

## **Women and Minority Inclusion in Clinical Research**

### **Reporting Data on Inclusion to NIH:**

If you are conducting clinical research (see definition in Section III. A., "DEFINITIONS" in the PHS 398), you must report the cumulative enrollment of subjects and their distribution by sex/gender and ethnicity/race, unless otherwise notified by your program official. For awards made as a result of New and Competing applications submitted after January 10, 2002, you should be using the **5/01 Inclusion Enrollment Report** ([PDF](#)) in progress reports. For awards made as a result of New and Competing Applications received before January 10, 2002, you may choose to report sex/gender and ethnicity/race composition using EITHER the format in the **4/98 Version of the Inclusion Table** ([PDF](#)) or the **5/01 Inclusion Enrollment Report** ([PDF](#)). If data were collected using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then the 5/01 Inclusion Enrollment Report ([PDF](#)) should be used. If you choose to report information using the 5/01 Inclusion Enrollment Report, you must continue to use this format for the remaining years of the project. See detailed instructions and frequently asked questions in <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

**Note: Reporting data on inclusion is not included in the two-page limit. If there is more than one study, provide a separate table for each study. Information about ethnic/racial subpopulations included in the study should be provided as an attachment to the table.**

**Changes to Targeted/Planned Enrollment.** If there are changes from the Targeted/Planned Enrollment originally approved for funding, you should submit a revised Targeted/Planned Enrollment page ([PDF](#)) and an inclusion enrollment report ([PDF](#)) describing data collected to-date. Explain the changes in a footnote or attachment to the report.

**NIH-defined Phase III Clinical Trial.** If you are conducting an NIH-defined Phase III Clinical Trial (see definition in Section III A. ["DEFINITIONS" in PHS 398](#)), you must report on the cumulative enrollment (as described above) and indicate if data analysis has begun for the trial. If so, you should report on progress made in conducting valid analyses for sex/gender and ethnic/racial differences.

**Foreign Populations:** If you are conducting clinical research outside of the US, you should design culturally sensitive and appropriate data collection instruments that allow participants to self-identify their ethnic and racial affiliation. These items, however, should be designed in a way that allows you, the investigator, to aggregate the information into the OMB minimally required ethnic and racial categories and complete the Inclusion Enrollment report. When completing the Inclusion Enrollment report, you should add an asterisk and footnote the report to indicate that data is from foreign participants. If your study includes both domestic and foreign participants, we suggest submitting two separate reports - one for domestic data and one for foreign data, with an asterisk and footnote explaining the foreign data.

**NOTE: The enrollment data by race may be lower than the Targeted/Planned enrollment by race because some individuals may designate that they belong to more than one race and will report under "More Than One Race" category. In this case, you may discuss these discrepancies in an attachment to the Inclusion Enrollment report.**

### **Standards for Collecting Data from Study Participants:**

When you are planning collection of data on ethnicity and race, as well as sex/gender, you should use the categories listed below in obtaining the data from individuals. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail shall be organized in such a way that the additional categories can be aggregated into these minimum categories for reporting data on ethnicity and race. Since a subject may refuse to self-identify either ethnicity or race, the collection form should have a category to collect this unknown/refusal response for both ethnicity and race. Using self-report or self-identification to collect this information, you should use two separate questions, with ethnicity information collected first followed by the option to select more than one racial designation. When reporting these data in the aggregate, you should report:

- (a) the number of subjects in each ethnic category;
- (b) the number of subjects who selected only one category for each of the five racial categories;
- (c) the total number of subjects who selected multiple racial categories reported as the "number selecting more than one race"; and,
- (d) the number of subjects in each racial category who are Hispanic or Latino.

NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>).

**NOTE: The 5/01 Inclusion Enrollment Report format is not designed for use as a data collection instrument. You should collect the data using instruments prepared for the study and use the information from the study database to fill out the enrollment report. Study participants who select two or more racial categories should be reported in the aggregate in the "More Than One Race" category. An example of a format for collecting information from a study participant can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page ([PDF](#)) in the PHS 398.**

The Office of Management and Budget (OMB) Directive No. 15 defines minimum standards for maintaining, collecting and presenting data on ethnicity and race for all Federal (including NIH) reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories:

"Hispanic or Latino," and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Reports of data on ethnicity and race should use these categories. NIH is required to use these definitions so that the data collected will allow comparisons to other Federal databases, especially the census and national health databases. The following definitions apply for the **ethnic** and **racial** categories.

### **Ethnic Categories:**

***Hispanic or Latino:*** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino".

***Not Hispanic or Latino***

### **Racial Categories:**

***American Indian or Alaska Native:*** A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community.

***Asian:*** A person having origins in any if the original peoples of the Far East, Southern Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

***Black or African American:*** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

***Native Hawaiian or Other Pacific Islander:*** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

***White:*** A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

**Ethnic/racial subpopulations.** In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

***Subpopulations.*** Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.

([http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)).

